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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,355	11/22/2004	Kenneth Hun Mok	930077-2010	4259

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,355	MOK, KENNETH HUN	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-11 remain pending.

Applicants' elections are acknowledged:

a) Pro-Tyr-Val in which all amino acids are of the "D" configuration;

b) a "pharmaceutical" composition (rather than a "food" composition);

c) the pharmaceutical composition is in the form of an injectable solution

✦

The title of the application is objected to. The title contains the phrase "retro iverso isomer". It appears that the phrase "retro inverso isomer" may be intended instead.

✦

On page 6 of the specification, reference is made to peptides of SEQ ID NO: 1, SEQ ID NO: 2, and SEQ ID NO: 3. This raises an issue in that if a "SEQ ID NO:" is referred to in the specification, the applicant is generally then required to provide a computer readable form (CRF), as well as a paper copy of the sequence listing. At the same time, however, a CRF listing is not required for peptides that consist of only three amino acids (as is the case with SEQ ID NOS: 2 and 3), and further, a CRF listing is not even permitted for a peptide that consists of only three amino acids. In addition, a CRF listing is not required for a peptide that

contains at least one "D" amino acid. Thus, applicants are in violation of one rule by *not* providing a sequence listing, but would run afoul of another rule if such a sequence listing were to be provided. [Applicants should note that it must be clear to the persons responsible for printing the final patent document that all rules and procedures have been complied with]. It would appear that the simplest way out of the dilemma would be to delete all references to SEQ ID NOS: 1, 2 and 3 (another means of identifying the peptides can then be created). If applicants feel so inclined, a sequence listing *may* be provided for SEQ ID NO: 1, but this will not actually become a requirement unless the actual phrase "SEQ ID NO: 1" appears in the specification.

For the sake of completeness, the form paragraph for sequence listings is provided below, but given the highly unusual situation, it does not necessarily apply:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §131 and 132.

✦

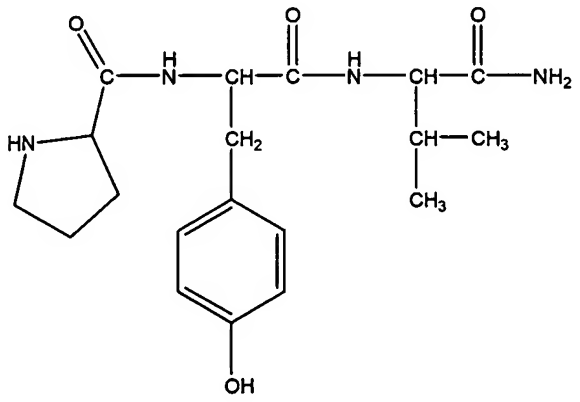
The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have provided data (page 6) which shows that certain compounds are effective to mitigate the increase in triglyceride levels that result from administration of olive oil to mice. Based on this data, applicants are asserting that the compounds to which the claims are directed can be used to treat hyperlipidemia (or at least to suppress triglyceride levels). As it happens, however, none of the compounds listed in table 1 falls within the scope of the claimed invention. For example, the peptide which is designated "SEQ ID NO: 2" is the following:



This compound, however, does not fall within the scope of the claims (because of the C-terminal amidation). Nor do any of the other compounds of table 1. Thus, applicants are attempting to extrapolate from one structure to another. The reality in peptide pharmacology is that minor changes in structure often eliminate activity. One cannot "predict" retention of activity when structures are altered.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Given the absence of working examples (that show the skilled cardiologist how to use the claimed compounds) and the unpredictability in the art, "undue experimentation" would be required to practice the claimed invention.

✦

Claims 1-11 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 is drawn to a pharmaceutical composition. A "composition", however, must contain at least two compounds (or a compound and another material or substance), otherwise it is a compound. Thus, claim 1 mandates the presence of a second compound, yet provides no clue at to what it might be. Is it a carrier? Is it another peptide? The same issue applies in the case of claim 7.

- None of claims 8-11 is actually subgeneric to claim 1 (or to claim 2, 3, 4, or 5). Claim 1 excludes the possibility that the C-terminal carboxyl group can be replaced with an amino group; claim 1 also excludes the possibility that the N-terminal amino group can be replaced with a carboxyl group. It is suggested that claims 8-11 be cancelled and that a new, independent claim be added which recites a structure (a structure in which contains the requisite malonyl group and a gem-diamino moiety). Particularly puzzling is how applicants intend to replace the "NH_2" group of Pro-Tyr-Val with a carboxyl group, given that proline does not actually have an NH_2 group.

✦

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800